510(k) Summary - Basic Information

1.1 Submitter

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DEC 0 4 2013

Date Prepared: June 26, 2013

1.2 Device Name

Device Name: *BM3/BM3 Plus*
Common Name: Multifunctional patient monitor
Classification Name: Cardiac monitor (including cardiotachometer and rate alarm) (870.2300, Class II)

1.3 Identification of Legally Marketed Device

Substantial equivalence is claimed to the Bionet BM3 Plus Patient Monitor (K082008) for all functionality other than $EtCO_2$. Substantial equivalence is claimed to the Larson & Toubro Star 50N (K103686) with respect to $EtCO_2$ functionality.

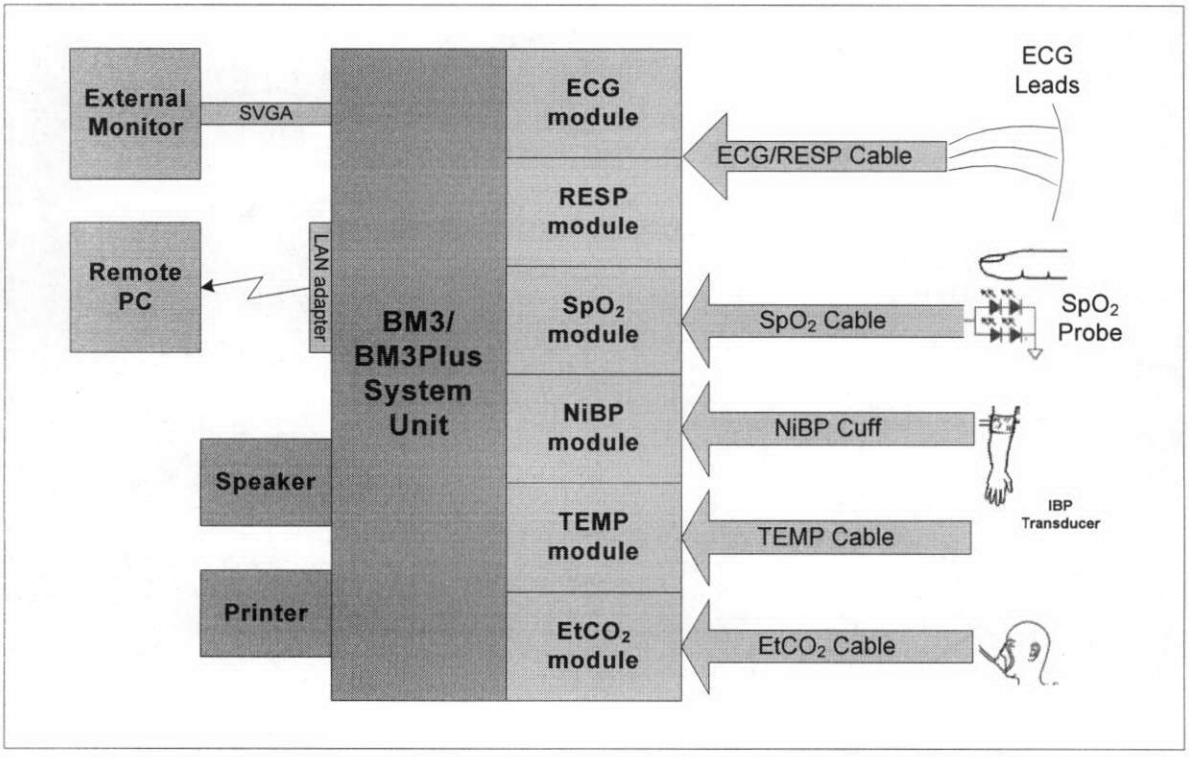
1.4 Device Description

The Bionet BM3/BM3 Plus Patient Monitor (BM3/BM3 Plus) is a multifunctional device that monitors vital signs of human patients from neonates to adults. Parameters monitored by BM3/BM3 Plus include end-tidal CO_2 ($EtCO_2$). electrocardiogram (ECG), pulse oximetry (SpO_2), pulse rate, noninvasive blood pressure (NIBP), temperature, and respiration, Data output is displayed in numeric and/or wave form(s) on a color LCD screen. Selected parameters and waves can also be shown in print via a built-in 58 mm thermal printer. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits.

BM3/BM3 Plus is compact and can be used in either stationary mode in all professional medical facilities or on the move in medical transport mode. Its energy source can come from AC input or lithium-ion battery. BM3/BM3 Plus LAN connection capability enables the device to be built into a monitoring system, so that one person can monitor several patients at a time.

Figure 1 depicts the BM3/BM3 Plus components that contribute to clinical utility in the form of functional blocks.

Figure 1: BM3/BM3 Plus Functional Components Contributing to Clinical Utility



1.5 Intended Use

The Bionet BM3/BM3 Plus Patient Monitor is intended for use by trained healthcare personnel to diagnose and monitor multiple physiological parameters of human patients. It can be used on patients from adults to neonates. The device is designed as a bedside and portable monitor that can operate in all professional medical facilities.

Physiological data include but are not restricted to: end-tidal CO_2, electrocardiogram, pulse oximetry, pulse rate, noninvasive blood pressure, temperature, and respiration. The data output is displayed on an LCD screen and/or through a built-in printer as numerical data or in waveform. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits.

The device is not intended for use as an apnea monitor, and it is not intended for use during MRI or CT scans.

1.6 Comparison to Cleared Devices

The Bionet BM3/BM3 Plus is substantially equivalent to the Bionet BM3 Plus Patient Monitor (K082008) for all functionality other than $EtCO_2$. It is substantially equivalent to the Larson & Toubro Star 50N (K103686) with respect to $EtCO_2$ functionality. Commercial information for Star 50N can be found at the following website: http://www.larsentoubro.com/lntcorporate/LnT_Offerings/Product_Template1.aspx?res=P_EBG_COFF_SBU_PROD&pid=2570&sbu=16

1.6.1 Comparison to BM3 Plus Patient Monitor (K082008)

Table 1 shows a tabular comparison of BM3/BM3 Plus to the BM3 Plus predicate device. Since the only difference is the $EtCO_2$ functionality, all other features are identical as shown in the comparison.

Table 1: Comparison of BM3/BM3 Plus Monitor with $EtCO_2$ to BM3 Plus

	BM3 Plus (K082008)	BM3/BM3 Plus
Device Type	Multifunction Patient Monitor	same
Target Population	Adult, pediatric patients, and neonates	same
Where used	Professional healthcare facilities including ambulatory.	same
Indication for Use	The Bionet BM3 Plus Patient Monitor is intended for use by trained healthcare personnel to diagnose and monitor multiple physiological parameters of human patients. It can be used on patients from adults to neonates. The device is designed as a bedside and portable monitor that can operate in all professional medical facilities. Physiological data include but are not restricted to: electrocardiogram, pulse oximetry, pulse rate, noninvasive blood pressure, temperature, and respiration. The data output is displayed on an LCD screen and/or through a built-in printer as numerical data or in waveform. The device may sound an alarm when a monitored parameter falls outside preset upper or lower limits. The device is not intended for use as an apnea monitor, and it is not intended for use during MRI or CT scans.	Same except also includes $EtCO_2$.
vital signs data/ sensor modules	• ECG/ ECG Module • respiration/ RESP Module • oximetry/ SpO_2 Module • non-invasive blood pressure/ NIBP Module • temperature/ TEMP Module.	Same except also includes $EtCO_2$ data from $EtCO_2$ Module.
Software	Embedded software monitors and displays data from vital signs sensor modules	Same except also includes $EtCO_2$.

1.6.2 Differences between BM3/BM3 Plus and BM3 Plus

The only difference between BM3/BM3 Plus and BM3 Plus is the hardware port for connecting to the $EtCO_2$ Module and the software to process data from that sensor.

1.6.3 Comparison to Star 50N (K103686)

Table 1 shows a tabular comparison of BM3/BM3 Plus to the Star 50N, which is the predicate for $EtCO_2$ functionality. The information for the Star 50N derives from its 510(k) summary and from information on the Larson & Toubro commercial website.

Table 2: Comparison to Star 50N with Emphasis on $EtCO_2$ Functionality

	Star 50N (K103686)	BM3/BM3 Plus
Intended Use	The STAR 5ON multi-parameter Patient Monitoring system is intended to monitor a single adult, pediatric and neonatal patient's vital signs at the bedside or during intrahospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (3 lead /5 lead), SpO_2, Respiration, Temperature, external optional Capnography (C02). it can also display the digital values of HR/PR, SPO2, RR, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2, and FiCO2. This monitor can also be connected to L&T Central Nursing Station (Skyline 55) and an external LCD-TFI display. The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals., The monitor is not intended for home use.	Same
Device Description	STAR 5ON is a multi-parameter patient monitoring system for continuous monitoring of the physiological parameters ECG (3/5 lead), Respiration, NIBP, IBP, Temperature, SpO_2 and external CO_2 (optional).	Same
Capture and Display Capabilities	STAR 5ON is a 6-channel monitor with 10.4" TFT display capable of displaying ECG, Respiration, SpO_2, C02, digital values of HR/PR, SpO_2, RR, Non-Invasive Blood pressure (Systolic, Diastolic and Mean), Invasive Blood Pressure (Systolic, Diastolic and Mean), Temperature, EtCO2 and FiCO2 readings.	Same except for display size and Invasive Blood Pressure
Capnography sensor	Microstream	Sidestream Mainstream
$EtCO_2$ displays	Parameter • $EtCO_2$ • $FiCO_2$ Capnography waveform	Same

1.6.4 Differences between BM3/BM3 Plus and Star 50N (for $EtCO_2$)

The difference between BM3/BM3 Plus and Star 50N is the capnography sensor technology. Star 50N uses Microstream technology and BM3/BM3 Plus uses Sidestream and Mainstream technology. The difference does not impact on safety or effectiveness because both the Star 50N technology and the Sidestream and Mainstream technologies have been previously cleared for the purpose of monitoring the level of carbon dioxide in exhaled breath ($EtCO_2$) to assess a patient's ventilatory status.

2. Performance Information

BM3/BM3 Plus was shown to conform to type testing for patient monitoring equipment by an independent testing laboratory. UL tested BM3 and BM3 Plus (both with $EtCO_2$ capabilities) for conformance to EN 60601-2-49 (*Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*) and found them to meet the technical requirements of the standard.

Clinical test is not applicable to BM3/BM3 Plus.

3. Conclusion

BM3/BM3 Plus and BM3 Plus have the same intended use and no technological difference other than the BM3/BM3 Plus $EtCO_2$ capabilities. BM3/BM3 Plus and Star 50N have the same intended use and no significant technological difference. Where BM3/BM3 Plus differs from the predicates, the differences do not affect the safety or effectiveness of BM3/BM3 Plus. Therefore, according to the principles FDA 510(k) notification, the subject device is substantially equivalent to the predicate devices with respect to safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 4, 2013

Noblitt & Rueland
c/o Mr. Marc Goodman
Senior Associate
5405 Alton Parkway
Suite A530
Irvine, CA 92604-3718 US

Re: K132033
Trade/Device Name: BM3/BM3 Plus Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm),
Regulatory Class: II (two)
Product Code: MWI
Dated: November 4, 2013
Received: November 6, 2013

Dear Mr. Marc Goodman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen D. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132033

Indications for Use Statement

510(k) Number
(if known)

Device Name BM3/BM3 Plus Patient Monitor

Indications for Use

The Bionet BM3/BM3 Plus Patient Monitor is intended for use by trained healthcare personnel to diagnose and monitor multiple physiological parameters of human patients. It can be used on patients from adults to neonates. The device is designed as a bedside and portable monitor that can operate in all professional medical facilities.

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The device is not intended for use as an apnea monitor, and it is not intended for use during MRI or CT scans.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen
Date: 2013.12.04 09:26:59 -05'00'